UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

SW

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,654	10/10/2001	David Matzinger	LIFE-045	9928

7590 04/22/2004

Carol M. LaSalle
BOZICEVIC, FIELD & FRANCIS, LLP
Suite 200
200 Middlefield Road
Menlo Park, CA 94025

EXAMINER	
MALLARI, PATRICIA C	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 04/22/2004

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/974,654	MATZINGER ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-26,28-41 and 43-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-6,8-26,28-41,44-64 and 83-108* is/are allowed.

6)☒ Claim(s) *65 and 76-82* is/are rejected.

7)☒ Claim(s) *1,66-75 and 83* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Objections

Claims 1, 65, and 83 are objected to because of the following informalities:

In claim1, on line 7 of the claim "insaid" should read "in said".

In claim 65, on line 6 of the claim, "(c)" should read "(b)".

In claim 83, on line 6 of the claim "type physiological" should read "type of physiological". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 65, 76, 78, 81, and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,682,233 to Brinda. Brinda, by teaching both that interstitial fluid is desired to determine the glucose concentration of an interstitial fluid sample (col. 1, lines 30-32) and that an interstitial fluid sample may be obtained at a site within a patient's skin layer but not through a dermal layer of the patient's skin (col. 4, lines 1-5; col. 6, lines 15-21), implicitly teaches a step of determining the type of physiological fluid at a site and a step of determining whether the site is suitable for sampling fluid for use in the analyte concentration determination test, as testing for glucose concentration determination in an interstitial fluid sample is the cited purpose for obtaining the interstitial fluid sample (col. 1, 30-33).

With regard to claim 76, the physiological fluid is accessed the site (col. 4, line 32; col. 6, lines 15-30).

With regard to claims 78, 81, and 82, the device 20 comprises an automated meter to determine the glucose concentration in the interstitial fluid sample (col. 4, lines 32-45).

Claims 65, 76-80 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Douglas et al. Douglas, by disclosing both that blood is desired for a test determining the glucose concentration in blood (col. 1, line 41; col. 6, lines 35-36) and that a blood may be obtained at a site such as a user's fingertips, earlobes or limbs (col. 1, lines 40-55), implicitly discloses both a step of determining the type of physiological fluid at the site and a step of determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test, based on the determined fluid type, as the testing the glucose concentration in a blood sample is the cited purpose for obtaining the blood sample (col. 1, line 41; col. 6, lines 35-36).

With regard to claim 76, the physiological fluid is accessed at the site (col. 5, lines 54-58).

With regard to claim 77, the site is stimulated to enhance the volume of fluid expressed from the site (col. 5, lines 49-54).

With regard to claims 78-80, the physiological fluid, which is blood, is transferred to an analyte concentration test strip 30 (col. 5, line 60-col. 6, line 27) and an automated meter performs the glucose concentration analysis (col. 6, lines 27-36).

Allowable Subject Matter

Claims 66-75 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-6, 8-26, 28-41, 44-64, and 83-108 are allowed.

The following is an examiner's statement of reasons for allowance:

With regard to claims 1-6, 8-15, 33-64, and 83-108, the prior art of record fails to teach or fairly suggest a means for or a step of determining whether a site is suitable for sampling physiological fluid based on a measure flow rate of physiological fluid at the site. US Patent No. 6,264,411 to Ishikawa et al. teaches an device comprising a physiological fluid flow rate characterization element 152 for measuring the flow rate of physiological fluid at a site (abstract; col. 9, lines 35-41) carried by a skin-piercing element 130 (abstract). Ishikawa lacks a means for determining whether a site is suitable for sampling physiological fluid based on the measured flow rate at the site. Therefore, no prior art exists teaching a method or apparatus of determining the suitability of a site of a site for sampling physiological fluid based on the flow rate of physiological fluid at the site.

With regard to claims 16-26, 28-41, and 43-48, the prior art of record fails to teach or fairly suggest a means for determining whether a site is suitable for sampling physiological fluid based on the determined fluid type. US Patent No. 5,769,791 to Benaron et al. teaches a device for determining the suitability of a site for sampling tissue comprising at least one tissue sample type characterization element 26 (col. 9, lines 37-42), at least one skin-piercing

element 30 (fig. 3D, col. 12, lines 26-29), where the characterization element distinguishes tissue by spectral characteristics and US Patent No. 6,230,046 to Crane teaches that venous blood and arterial blood are tissue types that are distinguishable based on their spectral characteristics. While the combination of Benaron with Crane teaches a means for determining whether the tissue matches a desired tissue type (col. 9, lines 64-69), the combined references fail to teach a means for determining whether the site is suitable for sampling physiological fluid.

With regard to claims 66-75, and 83-102, the prior art of record fails to teach a method of determining a suitable sampling site comprising the steps of determining the type of physiological fluid at a site by characterizing either the pulse or hemoglobin at the site and determining whether the site is suitable for sampling fluid for use in the analyte concentration determination test, based on said determined fluid type.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari at the telephone number (703) 605-0422. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari
Assistant Examiner
Art Unit 3736

Mary Beth Jones
Acting SPE
AU 3736